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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,727	10/28/2003	Rush E. Simonson	080083.00004	6338

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EXAMINER

ARAJ, MICHAEL J

ART UNIT PAPER NUMBER

3732

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,727	SIMONSON, RUSH E.	
	Examiner	Art Unit	
	Michael J. Araj	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 20, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/15/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Examiners restriction mailed on May 27, 2005 is withdrawn. A new restriction was made over the phone on June 28, 2005 between apparatus (claim 1-10) and method (11-20) where an election was made.

Applicant's election without traverse of claims 11-20 in the reply filed on June 20, 2005 is acknowledged.

Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected apparatus, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 27, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bullivant (U.S. Patent No. 5,507,816) in view of Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3).

Art Unit: 3732

Bullivant et al. discloses a surgical method for replacing damaged fibrocartilage in the vertebrae anteriorly where the damage fibrocartilage is removed to create an intervertebral space. Superior and inferior support plates (10 and 14) are inserted into the intervertebral space with the guide of a channel (Col. 4, lines 11-16) and a cushioning member (12) is placed between them to replace the fibrocartilage and absorb forces applied to the intervertebral space. Bullivant et al. also discloses that the supports have an offsetting lip portion (24) that limits the insertion of the implants into the intervertebral space. Bullivant et al. discloses the claimed method except for accessing the vertebrae posteriorly. Peckett et al. teaches that spinal surgery is best performed through a posterior approach (page 217, lines 1-2). It is disclosed that a disadvantage of the anterior approach as opposed to the posterior approach is the potential for visceral or vascular damage (page 216, lines 38-40). Therefore, it would have been obvious to one skilled in the art at the time the method was created to access the vertebrae posteriorly in view of Peckett et al., in order to provide an intervertebral disc endoprosthesis adapted to be inserted posteriorly, achieve long wear life, eliminate posterior spinal pathology and eliminate the need for facet joints.

Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bullivant (U.S. Patent No. 5,507,816) in view of Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) as applied to claim 15 above, and further in view of Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5).

Art Unit: 3732

The combination of Bullivant in view of Peckett et al., as applied to claim 15, discloses the claimed invention except performing a partial discectomy that includes removing the adjacent facets that would allow posterior access of the superior and inferior vertebrae at the desired site location of the implant. Wong et al. teaches a facetectomy to give access to the implant location. They also teach that hemi-facetectomy are preferred because near-total or total removal of the facets could significantly compromise vertebral stability and successful interbody fusion. (Page 575, Col. 2, lines 16-22) It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as modified by Peckett et al. to only remove the spinous process and the inferior articular process of the superior vertebrae and the superior articular process of the inferior vertebrae in view of Wong et al.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bullivant (U.S. Patent No. 5,507,816) as modified by Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5), as applied to claim 11 above, and further in view of Beer et al. (U.S. Patent No. 5,458,642).

The combination of Bullivant, Peckett et al. and Wong et al. discloses the claimed method except for the cushioning member being a coil spring. Beer et al. discloses a coil spring (13) to act as a cushioning member in the vertebral implant. It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as

Art Unit: 3732

modified by Peckett et al. and Wong et al., to have the cushioning member be a coil spring in view of Beer et al. because the coil spring distributes forces acting on the disc between the springs and allows for normal movement of the vertebrae.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bullivant (U.S. Patent No. 5,507,816) as modified by Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) and Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5), as applied to claim 11 above, and further in view of Gauchet et al. (U.S. Patent No. 6,579,320).

The combination of Bullivant, Peckett et al. and Wong et al. discloses the claimed method except for the cushioning member being a dampening matrix comprising a hydrogel core positioned within a constraining jacket. Gauchet et al. discloses a hydrogel core (16) dampening matrix positioned within a constraining jacket (26) to act as a cushioning member in the vertebral implant. It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as modified by Peckett et al. and Wong et al., to have the cushioning member be a dampening matrix comprising a hydrogel core positioned within a constraining jacket in view of Gauchet et al. because this allows the prosthesis to imitate the mechanical properties of a healthy natural intervertebral disk.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bullivant (U.S. Patent No. 5,507,816) as modified by Peckett

Art Unit: 3732

et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) and Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5), as applied to claim 11 above, and further in view of Paes et al. (U.S. Patent No. 6,436,142)

The combination of Bullivant, Peckett et al. and Wong et al. discloses the claimed method except for the cushioning member being two rounded inserts that are interconnected by a screw. Paes et al. discloses two rounded inserts (48) interconnected by a screw (28) to act as a cushioning member in the vertebral implant. It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as modified by Peckett and Wong et al., to have the cushioning member be two rounded inserts that are interconnected by a screw in view of Paes et al. so that proper stabilization could be made in the vertebral column.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

Art Unit: 3732

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MJA


EDUARDO C. ROBERT
PRIMARY EXAMINER